

GUIDELINES FOR PARTICIPATION IN PUBLIC MEETINGS FOR ALL NEW PUBLIC REQUESTS FOR REVISIONS TO THE HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS)

The purpose of the Public Meetings is to provide a forum for the general public to present information regarding specific Healthcare Common Procedural Coding System (HCPCS) coding requests for new products, supplies and services. The meeting also provides an opportunity to obtain industry and public reaction to the preliminary coding recommendations of the CMS HCPCS Workgroup, as well as CMS' preliminary recommendations regarding payment methodology. Coding decisions related to the Medicare and Medicaid programs internal operating procedures are reviewed internally, and are not included in this forum.

ROLE OF THE PUBLIC MEETINGS FOR ALL NEW REQUESTS, RELATIVE TO THE OVERALL HCPCS CODING PROCESS

The agenda for Public Meetings will consist of HCPCS coding requests for new products, supplies, and services that have been submitted through the HCPCS coding review and recommendation process. The specific items on each public meeting agenda will be posted on the HCPCS web site at: www.cms.hhs.gov/medicare/hcpcs. The public meetings are open to the public on a space-available basis. The meetings have typically been attended by representatives of medical equipment manufacturers and suppliers; government relations, regulatory and compliance specialist personnel from various provider organizations; industry consultants; and CMS staff. Applicants who submitted a code request for a product that appears on the public meeting agenda are welcome to attend, however their attendance is not mandatory.

The preliminary recommendations of the CMS HCPCS workgroup regarding coding requests, and CMS' preliminary payment methodology decisions, will be presented at the public meetings. After the public meeting, the CMS HCPCS workgroup will reconsider its preliminary coding recommendations, and CMS staff will reconsider its pricing recommendation, in view of information presented at the public meeting. No decisions are made at the Public Meetings. The HCPCS Workgroup is the entity that maintains the permanent HCPCS Level II codes, and is the final decision-making authority concerning requests for permanent HCPCS Level II codes. The Public Meetings are designed for all manufacturers and others to present additional information, clarify issues, and offer supporting or opposing perspectives regarding CMS' preliminary decisions. Final coding decisions are not made at the public meetings. Final payment decisions are made by CMS, in accordance with the Medicare Statute and regulations.

General information about the HCPCS coding process, the standard HCPCS code request format and detailed instructions can be found on the official HCPCS web site at: www.cms.hhs.gov/medicare/hcpcs. The official update of the HCPCS code system is available as a Public Use File and can be downloaded for free at: www.cms.hhs.gov/medicare/hcpcs.

ADDITIONAL OPPORTUNITIES FOR PUBLIC INPUT

All public requests for HCPCS Level II codes that have been submitted through the HCPCS coding review and recommendation process are listed on the HCPCS web site at: www.cms.hhs.gov/medicare/hcpcs. Comments, recommendations and inquiries are welcomed, and may be submitted via e-mail to www.cms.hhs.gov/medicare/hcpcs or via regular mail to the HCPCS National Panel, c/o Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop C5-08-27, Baltimore, Maryland 21244.

Comments and recommendations regarding these items may also be made in person at the Public Meetings. Comments will be considered if they are received by the end of the Public Meeting at which they are discussed.

MEETING LOCATION

Public Meetings are held in the Auditorium at the
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Meeting participants are responsible for arranging and funding their own travel and lodging.

NOTIFICATION OF PUBLIC MEETINGS, CONTENT OF THE AGENDA, AND MEETING SUMMARIES

Notice of Public Meetings for All New Public Request for Revisions to the HCPCS Coding and Payment Determinations appears in the Federal Register at:
www.access.gpo.gov/nara/index.html .

Public Meeting dates, agendas and related materials, registration information and meeting summaries are published at www.cms.hhs.gov/medicare/hcpcs. Agendas will be posted within 4 weeks of each meeting. A meeting summary will be posted by the end of July 2005.

It is the responsibility of the applicant and the general public to monitor the appropriate web sites for announcements and other information related to the Public Meetings.

SELECTING AGENDA ITEMS FOR PUBLIC MEETINGS

Items are placed on a Public Meeting agenda for New Requests if the application for the item was complete and submitted timely to the National HCPCS process in the current coding cycle.

MEETING DATES AND TIMES, CALENDAR YEAR 2005

Given the expansion of the public meeting process, we have scheduled additional meeting time for 2005. The following 8 dates, June 7, 8, 14, 15, 16, 21, 22, and 23, 2005

have been reserved for the meetings. We may not need all 8 days. Once the review and coding recommendation process is underway, we will have a firmer idea of the exact number of days needed to schedule the public meetings. We will consider each meeting individually, and we may modify the meeting dates and times.

Final confirmation of meeting dates and times, and agenda items will be posted three weeks in advance of each scheduled meeting, on the official HCPCS website at www.cms.hhs.gov/medicare/hcpcs. Each meeting day will begin at 9 a.m. and end at 5 p.m., E.S.T. However, because it is impossible to anticipate whether all presentations will fill their allotted time period (e.g. 15 minutes for Primary Speakers; 5 minutes or “5-Minute Speakers”), we cannot commit specific items to specific time frames, and we can only estimate the amount of meeting time that will be needed. Meetings may end earlier than 5:00 p.m. Meeting participants should arrive early and plan on the meeting commencing promptly at 9:00 a.m., and speakers simply need to arrive prepared and wait until it is their turn to speak.

ON-LINE REGISTRATION CLOSES MAY 23, 2005 FOR ALL PUBLIC MEETINGS IN CALENDAR YEAR 2005

REGISTERING TO ATTEND A PUBLIC MEETING

Registration may be completed on-line at: www.cms.hhs.gov/medicare/hcpcs. If you do not have internet access you may contact one of the Public Meeting Coordinators, Jennifer Carver at 410-786-6610 or Gloria Knight at 410-786-4598.

Upon completing on-line registration, you will automatically receive a confirmation. If you register by phone, a CMS staff member will confirm your registration by phone, fax or email. **Please bring your confirmation and photo identification with you to the meeting**, (refer to Security information below).

On-line registration will not be accessible after May 23, 2005. Individuals who do not have internet access, or who have missed the deadline for on-line registration, may register by phone by contacting Jennifer Carver or Gloria Knight. The deadline for phone registration for all meetings is May 31, 2005. **Due to heightened national security, only registered individuals will be allowed to enter the building.**

Registration information is used to generate a list of attendees. The names of individuals who have registered will appear on the attendee list. This list is used by Security guards to permit access into the building. It is also used to generate meeting sign-in sheets.

REGISTERING TO SPEAK AT A PUBLIC MEETING

Primary Speakers:

The entity that requested the modification to the HCPCS coding system for a particular agenda item may designate one “primary speaker” to make a presentation of a maximum

of 15 minutes. Fifteen minutes is the total time interval for the presentation, and must incorporate the demonstration, set-up, and distribution of materials. In establishing the Public Meeting agenda, CMS may group multiple, related requests under the same agenda item. In that case, CMS will decide whether additional time will be allotted, and may opt to increase the amount of time allotted to the speaker by increments of less than 15 minutes. In other words, the amount of time allotted to aggregate proposals might not be expanded exponentially by the number of requests.

Primary Speaker Responsibilities:

- **No later than 15 days in advance of the meeting:**

- Register to be a Primary speaker by personally notifying one of the Public Meeting Coordinators, Jennifer Carver at 410-786-6610 or Gloria Knight at 410-786-4598.
- Upon registering to be a Primary Speaker, indicate your needs for audio/video support. We offer an extensive array of audio and visual support options, (see below).

AV Options:

Audio Cassette Tape Playback

Assisted Listening Device

Video Tape playback (standard VHS or SVHS)

DVD playback

35mm slides (we can display slides through the projection system by use of a slide to video converter that is housed in the control room. Slides should be preloaded in Kodak-style carousel trays)

Computer Display (compatible with CMS standard programs - check in advance with the meeting coordinator)

Computer Interface (we can interface the video projection system with most laptop computers equipped with a standard VGA output connector)

Document and/or overhead projector (overheads or hard copy pages can be projected from the control room)

- **No later than 10 days in advance of the meeting:**

- Register on-line to attend the meeting.

- **No later than 7 days in advance of the meeting, Primary Speakers:**

- Provide a brief, written statement to Jennifer Carver or Gloria Knight regarding the nature of the information that will be presented at the meeting.

- Provide to Jennifer Carver or Gloria Knight any tape or disk file you intend to use at the meeting. In order to avoid disruption of the meeting and ensure compatibility with our systems, tapes and disk files are tested and arranged in speaker sequence in advance of the meeting. We are only able to accommodate tapes and disk files that are received timely by the meeting coordinator.

• **On the day of the meeting:**

- Primary speakers may bring handout materials with them, and distribute them at the meeting. Any materials distributed at the meeting should also be provided for review by the CMS HCPCS workgroup. For that purpose, we request that at least 35 additional copies be provided, on the day of the meeting. Handout and demonstration materials may not be shipped in advance of the meeting.
- Provide a written summary of your statement. State whether you support or disagree with the preliminary recommendation of the CMS HCPCS Workgroup and if you disagree, briefly summarize the reason(s) why.
- All speakers must declare in their oral presentation and in their written summary whether or not they have any financial involvement with the manufacturers or competitors of any items or services being discussed. This includes any payment, salary, remuneration, or benefit provided to the speaker by the manufacturer.

“5-Minute” Speakers:

Meeting attendees will be permitted to sign up at the meeting, on a first-come, first-serve basis, to make 5-minute presentations on individual agenda items. Based on the number of items on the agenda and the progress of the meeting, a determination will be made by the meeting coordinator and the meeting moderator, regarding how many 5-Minute speakers can be accommodated. In order to offer the same opportunity to all attendees, 5-Minute speakers may only register the day of the meeting, and not in advance of the meeting.

5-Minute speakers are required to submit, on the day of the meeting, a brief (one to two page) summary of their presentation.

All speakers must declare at the meeting as well as in their written summary whether or not they have any financial involvement with the manufacturers or competitors of any items or services being discussed. This includes any payment, salary, remuneration, or benefit provided to the speaker by the manufacturer.

GUIDANCE TO SPEAKERS FOR AN EFFECTIVE PRESENTATION

We have established, based on experience, the following tips for an effective presentation:

Information that is helpful:

State your name, relationship to the applicant and to the manufacturer, and declare any financial involvement with the manufacturer or competitors of any items being discussed. React specifically to the individual coding recommendation and state whether you support or refute it. If you disagree with the recommendation, provide substantiating information and explanation, and offer a recommendation as to how to correct it. Focus

on factual information and objective, supporting documentation. Information that is in addition to that already provided in the application may help to make a point. The CMS HCPCS Workgroup has evaluated the requests that appear on the Public Meeting agenda, arrived at and published its preliminary coding recommendation. The Public Meeting forum is an opportunity to provide additional information that may convince the CMS HCPCS Workgroup to reconsider its preliminary recommendation. Blanket dismissal of coding recommendation(s) or simply reiterating the original request without responding directly, and thoughtfully, to each individual preliminary coding recommendation does not help the workgroup to understand why the recommendation is unsatisfactory, or how or why it should be changed.

The focus of your presentation should be to convince the audience as to the reasons why your product is not adequately described by existing HCPCS code categories, and that your product fits the criteria for revising the HCPCS coding system, as described in a document entitled “Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures” at: www.cms.hhs.gov/medicare/hcpcs. Describe who will and who will not benefit by the use of the item.

Information that is not helpful:

Keep in mind that HCPCS codes identify categories of like products. The assignment of a HCPCS code does not guarantee, or even imply, that a product or service is covered by any insurer. HCPCS decisions and coverage determinations are completely separate processes. Coverage determinations are not part of the HCPCS coding decision-making process or part of the Public Meeting forum. Therefore, testimonials and discussions about medical necessity or efficacy are not beneficial, and may detract from the purpose of the meeting. It is inadvisable to expose at-risk patients for the purpose of providing testimony.

The Public Meetings are not directed to the attention of buyers of medical products. Therefore, promotional information, or a “sales pitch” that does not address uniqueness of the product category is inappropriate.

Timing of presentations:

Speakers may take less, but not more than the amount of time allotted (15 minutes for Primary Speakers, 5 minutes for “5-Minute” Speakers). Speakers may not give away, assign or yield unused time. Unused time is automatically forfeited to the moderator. Only the moderator may call speakers. Speakers may not call other speakers.

In fairness to all speakers as well as to the audience, the moderator will end all presentations precisely at the end of their allotted time. Therefore, it is helpful to rehearse and time presentations so to ensure that key points are made within the allotted time.

The moderator reserves the right to interrupt to preserve the order of the meeting for the benefit of the audience.

WRITTEN COMMENTS FROM MEETING ATTENDEES

We welcome the written comments of other persons in attendance at the meeting, who did not have the opportunity to or did not care to make an oral presentation. These written comments should be submitted at the meeting.

All speakers (Primary Speakers and 5-Minute Speakers) are required to submit, on the day of the meeting, a brief (one to two page) summary of their presentation.

SPECIAL NEEDS

Persons attending the meeting who are hearing or visually impaired and have special requirements or a condition that requires special assistance or accommodations should make a notation to that effect on the registration form, or directly contact one of the Public Meeting Coordinators, Jennifer Carver (410) 786-6610 or Gloria Knight (410) 786-4598, **by the registration deadline**. Advance notice is necessary in order for us to make arrangements to accommodate special needs.

SECURITY ON THE DAY OF THE MEETING

All meeting attendees should bring with them government issued photo identification, and a copy of their pre-registration confirmation. The Public meetings are held in a government building; therefore, security measures will be applicable. Photo identification must be presented upon entering the complex and again upon signing-in at the security desk. Security Officers may deny access to the building complex to persons without proper identification. Meeting attendees must also provide registration information (confirmation of meeting registration). Meeting attendees should allow approximately 15 minutes to clear security upon arrival.

Any items brought to the building for the purpose of being demonstrated at the meeting must clear security. CMS does not assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety or security clearance of any belongings or items used for demonstration, or for their timely arrival at the meeting. We ask presenters to consider the practicality of bringing in large equipment or multiple pieces of equipment, and whether other means of demonstration, such as video or pictures, may be useful, less distracting, and much more easily managed.

In the event that the National Security level is elevated to “code red”, please phone CMS at 410-786-6010. In the event the building is operating under a code red this means the building will be closed and the Public Meeting will be cancelled.

MEETING SIGN-IN ONCE ON-SITE

On-site sign-in for visitors who have registered to attend the meeting will be held 30 minutes prior to the starting time of each meeting.

FAQ's

WHO MAY ATTEND THE PUBLIC MEETINGS?

The public is invited to attend CMS' Public Meetings. Members of the CMS HCPCS Workgroup and CMS staff who have a special program interest in a topic may attend, based on their availability. Entities who submit requests that are being discussed at the meeting and their competitors might attend. Attendance at the Public Meetings is voluntary and optional.

IS ATTENDANCE MANDATORY FOR APPLICANTS WHO HAVE AN ITEM ON THE AGENDA?

No. Attendance is completely voluntary. Whether or not the requesting entity is represented at the meeting, all agenda items will be presented with a description of the request and the preliminary recommendation of the CMS HCPCS Workgroup (as published with the agenda on the official HCPCS website at www.cms.hhs.gov/medicare/hcpcs).

ARE DECISIONS MADE AT THE PUBLIC MEETINGS?

No. The Public Meetings are not CMS HCPCS Workgroup meetings. The CMS' Public Meeting forum provides an opportunity for a requester to speak to CMS and to the Public, and an opportunity for CMS to hear from requester and public, and balance competing points of view. It is an opportunity for general public and competitors to participate in a discussion of HCPCS coding for new requests

Information provided at the CMS Public Meetings is shared with members of the CMS HCPCS Workgroup at a subsequent workgroup meeting. The workgroup reconsiders its preliminary recommendation in light of any new information provided, and formulates its final coding decision. CMS is the final decision making authority concerning requests for permanent HCPCS Level II codes.

THE AGENDA DOES NOT INCLUDE TIMES. HOW DO PARTICIPANTS KNOW EXACTLY WHEN SPECIFIC ITEMS WILL BE DISCUSSED?

It is impossible to anticipate whether all presentations will fill their allotted time period (e.g., 15 minutes for Primary Speakers; 5 minutes for "5-Minute Speakers"), therefore we cannot commit specific items to specific time frames. We ask that speakers arrive prepared, plan on the meeting commencing promptly at 9:00a.m, E.S.T., and simply wait until it is their turn to speak. Meetings are scheduled to adjourn at 5:00 p.m.; however, because we can only estimate the amount of meeting time that will be needed, meetings may adjourn earlier than 5:00 p.m.